

In re Application of: Rottenberg et al  
Serial No.: 10/597,666  
Filed: June 20, 2007  
Office Action Mailing Date: March 24, 2009

Examiner: Susan Shan SU  
Group Art Unit: 3761  
Attorney Docket: 34955

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1, 3-6, 9-12 and 15-19 are in this Application. Claims 1, 3-6, 9-12 and 15-19 have been rejected. Claims 1, 10, 11 and 17 have been objected to. Claims 1, 3, 10, 11, 15 and 17 are amended herewith.

#### ***Claim Objections***

The Examiner has objected to claims 1, 10, 11 and 17 for lack of an antecedent basis. The Examiner states that there is no mention of a structure called "cover" and thus, "said cover" should be changed to --said flow regulating mechanism--.

Applicant has now amended claims 1, 10 and 11 to correct lack of antecedent basis. Claims 1, 10 and 11 now define the shunt as being covered in a manner that maintains it always open.

In claim 17, "in said body" should be removed since there is no prior recitation of "a body" and said chambers, should be changed to --said atria--.

Claim 17 has now been amended to correct these deficiencies.

#### ***Claim Rejection - 35 USC 101***

The Examiner has rejected claims 1, 10 and 11 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The Examiner states that when the claims recite a device or an apparatus with certain elements being "attached to" the human body positively sets forth a claim on a human body which makes it non-statutory.

Claims 1, 10 and 11 have now been amended in accordance to the kind suggestions made by the Examiner.

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***Claim rejections - 35 USC 103***

The Examiner has rejected claims 1, 3-4, 9-10, 17 and 19 under 35 USC 103(a) as being unpatentable over Wolf et al. (US2004/0147869). The Examiners rejections are respectfully traversed. Claims 1, 10, 11 and 17 have now been amended.

The Examiner states that Wolf et al. teach a pressure regulating device for enabling fluid flow between two chambers but does not specifically teach that the two chambers are the left and right heart atria. The Examiner further states that Wolf et al. disclose that a heart wall can be a septum of a heart.

Wolf et al. teach various configurations of conduits for allowing communication of bodily fluids from one portion of a patient's body to another. Specifically, Wolf et al. teach conduits that can be used to form "a coronary artery bypass by allowing blood communication between the left ventricle and the coronary artery or between a proximal portion of the coronary artery and a distal portion of the coronary artery" (abstract). Wolf et al. do not teach or suggest regulating pressure between two heart chambers or specifically between two atria.

Although Wolf et al. mention a heart septum as a possible target tissue for implantation of a conduit, such a septum is mentioned once and in the context of tissue which can be traversed in order to achieve the flow path desired (from a ventricle to an artery).

Section [0112] of Wolf et al. which is cited by the Examiner as evidence of disclosure of a septum recites the following:

"In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the intrapericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a

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left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even non-cardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc." (Emphasis added)

One of ordinary skill in the art would clearly understand that in reciting "septum" Wolf et al. imply that a conduit from a ventricle to an artery can be routed through a septum and that such routing would be through a ventricular septum and not a conduit that fluidly connects the two atria through a septum thereof.

Thus, Wolf et al. teach septum as tissue through which a conduit can be routed and not in the context of a conduit which is configured for septal implantation for the purpose of regulating pressure between atria. Since Wolf et al. do not teach regulation of atrial pressure, no other interpretation for this use of a "septum" can be made.

Thus, Applicant believes that independent claims 1, 10 and 17 are patentable with respect to the teachings of Wolf et al. thereby rendering any claims directly or indirectly dependent from these claims also patentable with respect to this prior art.

Notwithstanding from the above, and with respect to claims 3 and 15, Applicant has now amended these claims to include limitation pertaining design features unique to the present shunt. Claims 3 and 15 now include the following limitation:

"said shunt being configured so as to protrude into said left atrium and/or said right atrium when implanted into said septum"

Such a configuration is illustrated in Figures 1C, 1H, 1L and 13A, of the instant application.

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Wolf et al. do not describe nor mention a shunt which protrudes into a lumen of an atrium, such a shunt configuration is advantageous when used in septal positioning since it prevents/minimizes tissue overgrowth which may clog the shunt and/or valve. Since Wolf et al. do not implant a shunt in a septum with openings into the atria, the advantages of such a configuration would not be known to Wolf et al. or to an ordinary skilled artisan privileged to the teachings of Wolf et al.

The Examiner has also rejected claims 5-6, 11-12, 15-16 and 18 under 35 USC 103(a) as being unpatentable over Wolf et al. (Ref 1) in view of Wolf et al. (US2002/0165606 - Ref 2)

As is argued above, Applicant strongly believes that claims 1, 10, 11 and 17 are patentable over Wolf et al. (Ref 1) in light of the fact that Ref 1 does not teach or suggest septal positioning of an atrial-pressure regulating shunt. Since Ref 2 is only relevant in as far as limitations pertaining to control mechanisms, Applicant believes that the independent claims pending in the application and the claims dependent therefrom are clearly patentable over the combination of Ref 1 and Ref 2.

In view of the above amendments it is respectfully submitted that claims 1, 3-6, 9-12 and 15-19 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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**Encl.:**

- Petition for Extension for Three (3) Months